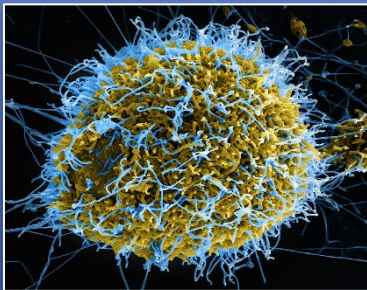
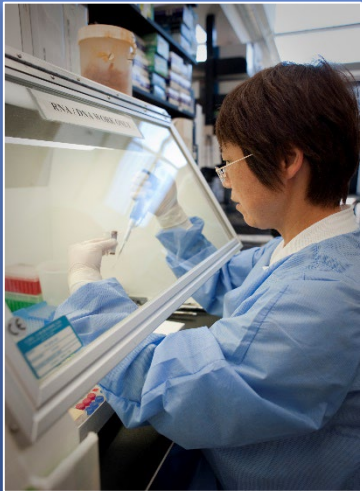
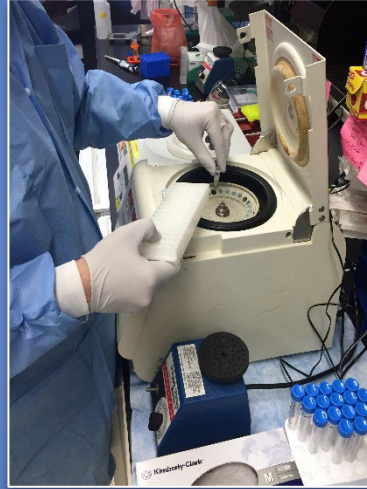
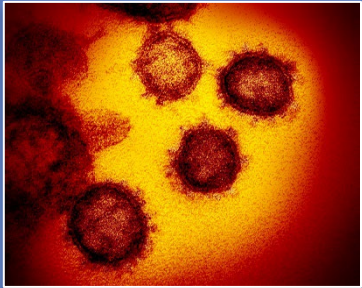


# 2022 Charge to the NSABB



Lawrence A. Tabak, D.D.S., Ph.D.  
Acting Director, NIH

Lyric A. Jorgenson, Ph.D., Acting  
Associate Director for Science  
Policy, NIH

NSABB Meeting - February 28, 2022



# USG Biosecurity Oversight Framework Review

- Biosecurity and safety are of paramount importance to the USG
- NIH promotes regular policy review to ensure oversight:
  - Keeps pace with scientific advances that may raise biosecurity concerns
  - Effectively balances science and security to safely enable lifesaving research
  - Is grounded in benefits while appropriately mitigating risks
- Charge focuses on U.S. biosecurity policy frameworks governing:
  - Research with enhanced potential pandemic pathogens
  - Dual Use Research of Concern

# Oversight of DURC & P3CO

- Dual Use Research Of Concern (DURC)
  - **USG Policy for Oversight of Life Sciences DURC** (March 2012) requires federal funding agencies to identify DURC in their research portfolios and work to mitigate risks as needed
  - **USG Policy for Institutional Oversight of Life Sciences DURC** (effective 2015) requires federally-funded research institutions to establish a system to identify DURC and work with funding agencies to mitigate risks as needed
- Potential Pandemic Pathogen Care and Oversight (P3CO)
  - **OSTP P3CO Policy Guidance** (2017) directs Federal departments and agencies to adopt a department-level, multidisciplinary, pre-funding review mechanism
  - **HHS P3CO Framework** (2017) ensures HHS department-level pre-funding review and evaluation of proposed ePPP research

## NSABB CHARGE

# Phase 1 - P3CO Policy Review and Evaluation

- Evaluate and provide recommendations on the effectiveness of the current oversight framework (OSTP Policy Guidance and process adopted by HHS) for research involving ePPPs including:
  - Scope, in terms of preserving benefits of ePPP research while minimizing potential biosafety and biosecurity risks
  - Considerations for supporting ePPP research internationally
  - Balancing considerations regarding security and public transparency when sharing information about research involving ePPP
- Consider Policy Guidance impact on research programs and institutions

## NSABB CHARGE

### Phase 2A – DURC Policy Review and Evaluation

- Evaluate and analyze the U.S. Government federal and institutional policies for the oversight of dual use research of concern (DURC) to:
  - Evaluate effectiveness in achieving their intent
  - Evaluate impact on research institutions and U.S. Government's ability to support research
  - Identify implementation challenges
  - Evaluate effectiveness with regard to publication, public communication, and dissemination of dual-use research methodologies and results

## NSABB CHARGE

### Phase 2A – DURC Policy Review and Evaluation *(cont.)*

- Reevaluate DURC definition, considering advances in life sciences research and convergence with other scientific disciplines/sectors

***DURC: Life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.***

- Evaluate effectiveness of DURC pathogen list and experimentation type construct to determine whether:
  - Approach sufficiently addresses future potential threats, across the spectrum of life sciences research
  - Approach is conducive to research risk-mitigation
  - Alternative approaches warrant consideration

NSABB CHARGE

## Phase 2B – P3CO Policy Review and Evaluation



- With regard to the *Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight*:
  - Evaluate Section 8 “Future Commitments” and provide recommendations on possible *P3CO Policy Guidance* incorporation into policy frameworks associated with any recommended revisions of the DURC policies

## Phase 2 – Flexible and Adaptive Approaches

- Throughout Phase 2, NSABB should consider flexible and adaptive governance approaches that:
  - Keep pace with scientific advances and evolving understanding of risks and benefits
  - Can coalesce and integrate existing governance guidance, or policy
  - Can be applied to mitigate risk not only from research of concern but other biosecurity and biosafety considerations



# Anticipated Timeline

- **March:** NSABB forms working group to address Phase 1
- **Late Spring:** Virtual listening sessions to gather public input
- **May/June:** NSABB forms working group to address Phase 2
- **Late Summer:** NSABB public stakeholder engagement meeting
- **December:** NSABB meeting to finalize draft report and recommendations

